

REMARKS

Reconsideration of this application is requested.

Claims 12-23 have been canceled. This obviates the Examiner's dependency objection against claims 14-23 as well as the Section 112 (second ¶) and Section 101 rejections thereof as set out on pages 6-7 of the action.

New claims 24 and 25, directed to treatment of the specific symptoms noted at page 3, lines 11-14 of the applicants' specification, have been added for consideration. These new claims are thought to be in proper statutory form and allowable over the prior art for the same reasons as the other claims herein as discussed below.

In the interest of minimizing issues, the applicants' main claim (claim 1) has been amended by deleting the reference therein to prevention. The applicants do not agree with the basis for the Examiner's objection to claiming prevention and make the indicated amendment without prejudice to later pursuing this aspect of the applicants' invention. For the present, however, it is believed that the indicated amendment of claim 1 obviates the basis for the Examiner's Section 112, 1st ¶ rejection of the applicants' claims. Accordingly, reconsideration of this rejection is requested.

The Examiner is respectfully requested to reconsider the Section 102(b) rejection of applicants' claims 1-11 as anticipated by Cook et al. (U.S. 5,827,885). With respect, it is submitted that Cook et al. do not anticipate the applicants' invention.

Cook et al. disclose a method of treating animals by maintaining or increasing the CD-4 and CD-8 lymphocyte cell populations or levels (see Col. 1, lines 16 to 20). There is only a general statement in Cook et al. that increasing levels of these cell populations can benefit an immune system. However, this does not tell the skilled person anything about what the benefits could be or give any indication that CLA could be useful in the treatment of the symptoms associated with a common cold. In fact, it is clear from the background discussion in the patent (see Col. 1, lines 25-51) that Cook et al. is primarily interested in weight loss.

The Examiner has referred to the disclosure in Cook et al. at Column 2, lines 30 to 50 to support the rejection of applicants' claims. However, the only *symptom* mentioned at this point of the patent is weight loss (see Col. 2, lines 39 to 40). Cook et al. cannot, therefore, be considered to specifically disclose the treatment of all

possible symptoms of all viral infections, much less the specific treatment contemplated by the applicants.

Indeed, in the examples, Cook et al. mentions reduction in *weight gain* in response to weight loss caused by an endotoxin, TNF or fowl pox virus (which belongs to the family poxvirus and is not involved in the common cold). This is the only symptom that is contemplated by Cook et al. and for which any data is provided. There is clearly no mention of the problem of the common cold in Cook et al.

Although Cook et al. states that viral infections have been shown to deplete CD-4 and CD-8 cells, the only viral infection that is mentioned in this context is HIV (see Col. 2, lines 6 to 9). Furthermore, viral infections are only referred to in Cook et al. insofar as they relate to the symptom of weight loss (see Col. 3, lines 29 to 33). This is also clear from Example 7, which includes the only data relating to the effects of CLA following infection with a virus. Cook et al. teaches that following infection with a virus, CLA can prevent the loss of weight gain. This does not amount to a disclosure of the treatment of the symptoms of the common cold as the applicants contemplate and claim.

Further indications that, as far as Cook et al. are concerned, the only adverse effects of viral infections that CLA can treat are anorexia and weight loss are provided at Column 9, lines 4 to 8 in Cook et al. Moreover, no evidence or data is provided in Cook et al. that would indicate that CLA could be effectively used against any virus other than fowl pox virus or against any symptoms other than weight loss. The statement at Column 9, lines 10 to 18 is purely speculative and the person skilled in the art would appreciate this. There could be no expectation for the skilled person that CLA would be effective in the treatment of a common cold from the disclosure in Cook et al.

The present invention relates, at least in part, to the surprising finding that conjugated fatty acids and derivatives thereof can be used to *treat* the symptoms of a common cold in a mammal. Some of these symptoms are listed in the present application and form the basis for new claims 24 and 25. There is no disclosure in Cook et al. of the ability of conjugated fatty acids to treat the symptoms of a common cold in a mammal as contemplated by the applicants and as called for in all of the pending claims, including the newly added claims 24 and 25.

The present application states that more than 200 viruses can cause the symptoms of the common cold and then lists the most important viruses as

coronaviruses, picornaviruses, rhinoviruses, coxackieviruses and adenoviruses (see page 1, lines 15 to 18).

Cook et al. mention some of these viruses at Column 9, lines 15 to 18 (in particular, coronaviruses, picornaviruses and adenoviruses). However, the disclosure of these viruses does not amount to a disclosure that CLA would be able to treat the symptoms of a common cold. Thus, the disclosure of the viruses themselves is not a disclosure of any illness that they could potentially cause. The effect of any virus will depend upon the host and infection with the virus will not necessarily lead to the symptoms of a disease if the immune response of the host is efficient at counteracting the virus, for example. Since there is no link between the viruses and any specific symptoms, such as those of the common cold, there can be no disclosure in Cook et al. that falls within the scope of the present claims or suggests the substance thereof.

Cook et al. refer to "adverse effects" of viruses but then only go on to indicate that adverse effects relate to weight loss (see Col. 2, line 26 and Col. 9, lines 4 to 5). The issue of weight loss in response to a specific viral challenge is clearly the focus of Cook et al.

Furthermore, the terms "coronaviruses", "picornaviruses" and "adenoviruses" encompass many different viruses that can cause many different diseases in birds or mammals and which are not necessarily related to the common cold.

Referring to the attached copies of pages from Introduction to Modern Virology (Dimmock and Primrose, Blackwell Science, 4th Edition, 1994, p. 342, 345 and 346), the term "picornavirus" is the name for a family of many different virus genera, some of which are responsible for diseases that are not related to the common cold. Thus, the "picornavirus" family includes, but is not limited to, the following genera: Cardiovirus (encephalomyocarditis (EMC) virus of mice), Aphthovirus (foot-and-mouth disease virus) and the Hepatitis A virus (of humans).

Coronavirus can cause avian infectious bronchitis and equine arteritis. Adenoviruses may cause diseases in the upper respiratory tract. There is no mention of the common cold as such.

Thus, a disclosure of "picornavirus" is not a disclosure of "rhinoviruses" not least because the term "picornavirus" can refer to many other viruses as well. There is certainly no indication in Cook et al. of which specific virus or viruses are intended by the term "picornavirus". Furthermore, Cook et al. do not indicate that any of the viruses mentioned (which include coronavirus and adenovirus) could be responsible

for or involved in the symptoms of the common cold or that CLA could counteract these symptoms. The terms "picornavirus", "adenovirus" and "coronavirus" in Cook et al. are not disclosed in relation to the common cold. Hence, there can be no disclosure of any technical effect that CLA has any relation to the common cold, which, of course, is the subject of the claimed invention.

Given the variety in the types of virus that can occur within a family or genus and their different effects, it is not possible to derive from the disclosure in Cook et al. that the virus will result in a common cold. The disclosure in Cook et al. is deficient as regards all of the features of applicants' main claim (claim 1) and thus is not novelty destroying.

As noted, Cook et al. do not mention the treatment of a common cold or indicate any symptoms associated with the common cold. Hence, there cannot be any link in Cook et al. between the common cold and the properties of conjugated linoleic acid (CLA). The disclosure of the families of viruses listed in Cook et al. is not necessarily a disclosure of a common cold for the reasons set out above and so does not provide any link between the treatment of a cold and CLA. The only adverse effects of the viruses contemplated in Cook et al. are the effects of anorexia and weight loss (see Col. 9, lines 4 to 5).

Furthermore, Cook et al. cannot be considered to be in any way an enabling disclosure for treating viral infections, or their symptoms, in general. The enabling disclosure in Cook et al., at most, is limited to avoidance of weight loss in chicks with fowl pox virus.

To summarize, therefore, Cook et al. do not disclose a mammal with a cold or the treatment of a cold with a conjugated fatty acid. There is no disclosure of the symptoms of the common cold in Cook et al. Hence, there is no indication in Cook et al. that CLA would be capable of treating the symptoms of a common cold such as those listed in the application at page 3, lines 7 to 14.

Since there is no disclosure of the ability of CLA to treat the symptoms of a common cold in Cook et al., the applicants submit that the subject matter of claim 1 and all the other claims herein, is novel and should be patentable. Clearly, there is no indication in Cook et al. that CLA could act as anything other than a specific agent for preventing weight loss. Thus, there is no indication in Cook et al. that CLA would be able to treat the symptoms of the common cold or any suggestion to use CLA or any other conjugated acid to treat a common cold.

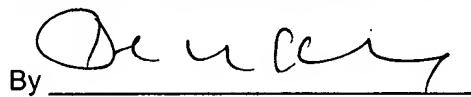
For reasons evident from the foregoing, the applicants respectfully submit that the Section 102(b) rejection of the claims herein should be withdrawn and all of the claims, including newly added claims 24 and 25, found to be patentable. All other objections having been dealt with, it is submitted that the application is in allowable condition and should be allowed.

Favorable action is requested.

Respectfully submitted,

MORGAN LEWIS & BOCKIUS LLP

By



Paul N. Kokulis  
Reg. No. 16773

Date: November 22, 2005

**Customer No. 09629**  
1111 Pennsylvania Avenue, N.W.  
Washington, D.C. 20004  
Phone: (202) 739-3000  
Facsimile: (202) 739-3001  
Direct: (202) 739-5455